REMARKS

I. Amendment

In this response, claim 1 has been amended to include the subject matter of claims 4 and 6 as originally filed. This change necessitated cancellation of claims 4 and 6 and modification of the dependency of claims 23, 24 and 26-28.

The amendment adds no new matter to the specification.

II. Discussion of the Rejection under 35 U.S.C. Sec. 102(e) over Lundberg

Claims 1-7, 9, 11, 12, 15-19, 21, 22, 29 and 31 have been rejected under 35 U.S.C. Sec. 102(e) as allegedly anticipated by Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection for three reasons 1) the cited art is directed to a different dosage form having different requirements from the presently claimed tablets; 2) the cited art does not recite sustained-release agents and 3) the cited art does not describe oral disintegration time. Each of these points will be discussed in the following paragraphs.

Different Dosage Form

The aspect of Applicants' invention as set forth in the pending independent claim 1 as amended is directed to orally disintegrable tablets of specified composition having a certain range of hardness strength and oral disintegration time. The goal of the invention (tablets as set forth in claim 1 as amended) is described succinctly on page 2, line 33- page 3, line 3 of the specification, where it is stated that "[t]o accompany an aging population and their changes in life environment, it is desired to develop an orally disintegrable solid preparation capable of being administered without water, retaining the convenience of use which is a characteristic of a tablet, and being administered on demand easily, anytime and anywhere, without water."

By contrast, the cited reference is directed to multiple unit effervescent tablets. The utilization of the effervescent tablets is described in col. 1, line 61 – col. 2, line 2 of the cited reference wherein it is stated that "[p]rior to being taken by the patient, an effervescent

composition is dissolved and/or dispersed in for example an aqueous medium, such as drinking water." The cited reference also states that "[e]ffervescent compositions usually contain, in addition to the active ingredient, a source of carbon dioxide (such as an alkaline carbonate or bicarbonate) and an acid (such as for instance citric acid)." in col. 2, lines 3-6.

To be perfectly clear, the tablets of the '770 patent dissolve in a glass of water, not in a patients' mouth. Those skilled in the art understand this, and would not look to a reference directed to effervescent tablets for direction when contemplating creation of tablets for oral dissolution. This is so because an effervescent tablet will be dissolved in a large amount of water, while an orally disintegrable tablet will be dissolved in only a minimal amount of water (saliva).

No Sustained-Release Agent

Moreover, the cited reference does not mention or include sustained release agents. Sustained release agents are the required second components of the fine granules in the tablets of claim 1.

No Measure of Oral Disintegration Time

Should further clarification be required, Applicants wish to draw the Examiner's attention to the fact that the time measured in the examples of the cited reference was *not* an oral disintegration time. It was an *effervescence* time. The Examiner is respectfully requested to compare the effervescence time test in the cited art (col. 18, lines 16-24 for example) to the oral disintegration time test as described in the specification (page 35, lines 18-20). The oral disintegration time of one minute or less recited in claim 1 is not disclosed by the cited reference.

Claims 4 and 6 have been cancelled. Claims 2, 3, 5, 7, 9, 11, 12, 15-19, 21, 22, 29 and 31 depend upon claim 1. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference for the reasons provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(e) over Lundberg.

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1-7, 9, 11-19, 21- 29 and 31 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in view of Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

Applicants hereby incorporate the comments of Sec. II above in defense of their invention.

The present invention, as set forth in claim 1 as amended is not obvious over the cited art for the reasons indicated above. The cited art does not teach or suggest the present invention, as it is directed towards tablets dissolved in water, not in a patients' mouth.

Claims 4 and 6 have been cancelled. Claims 2, 3, 5, 7, 9, 11-19, 21- 29 and 31 depend upon claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious in view of the cited reference for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg.

IV. Discussion of the Additionally Cited Art

Applicants wish to thank the Examiner for bringing the additionally cited art of Koyama *et al.* to their attention. Applicants have reviewed the reference and do not believe that it detracts from the patentability of the present invention.

Applicants note that that Makino *et al.*, Tomohisa *et al.* and Depui *et al.* (references A, B and N on the form PTO-892) are already of record in this application.

V. Conclusion

Reconsideration and allowance of the claims is requested in light of the arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: March 8, 2004

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293
Attorney for Applicants
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date March 8, 2004 .

Express Mail Label No. EV 410710221 US

Gail L. Winokur

Printed Name: Gail L. Winokur